REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.114, are respectfully requested.

Claims 1-10, 12, 22, 26, 40, 42-44, 46, 50, 53, 54, 56, 58, and 63-108 are pending in the application. Claims 1-10, 12, 40, 43, 44, 46, 50, 70-84, 98, 99, 104, 105 are withdrawn from consideration. Claims 22, 26, 42, 53, 54, 56, 58, 63-69, 85-97, 100-103, and 106-108 are under consideration and stand rejected.

Claims 2, 4, 22, 43, 44, 53, 54, 64, 66, 67, 71, 73, 81, 82, 85, 87, 88, 92, 94, 99, 100, 103, 105, and 106 have been amended to strike out the recitation of 95% identity between the sense and antisense strand the nucleic acid of interest. Claims 42 and 86 have been amended to correct an obvious clerical error. Claim 46 has been amended to correct the claim dependence in view of the previous cancellation of claim 45.

No prohibited new matter has been introduced by way of the above amendments. Applicants reserve the right to file a continuation or divisional application on subject matter canceled by way of this Amendment.

Applicants thank the Examiner for the courtesy of a personal interview June 2, 2006 during which the Amendment and Reply dated May 10, 2006 and the rejections set forth in the Office Action of November 10, 2005 were discussed. The function and effect of the introns recited in the claims was discussed.

Rejections under 35 U.S.C. § 112

A single rejection has been maintained. Claims 22, 26, 42, 53, 54, 56, 58, 63-69, 85-97, 100-103 and 106-108 have been rejected under 35 U.S.C. § 112, first paragraph, for

allegedly failing to comply with the written description requirement. The Office has alleged that the specification and claims do not adequately describe the broad genus comprising chimeric DNA that, when transcribed, yield two annealing RNA strands (1) sharing between 95-100% sequence identity with (2) any target gene of interest and which further comprise (3) any intron sequence heterologous to the sense strand. OFFICE ACTION MAILED JUNE 22, 2006 at 3, lines 8 - 11. The Office has alleged that the written description in the specification is not adequate to support the entire claimed genus of chimeric genes. However, the Office has not identified any particular deficiency in the written description that would cause a person of ordinary skill in the art to doubt that the general structures of the chimeric genes that are described in the specification and recited in the claims are not adequate to support the entire genus when combined with the knowledge of any of the myriad known genes to which the principles of the invention may be applied. The rejection is respectfully traversed.

Concerning whether the application provides written description for chimeric DNA that when transcribed yields yield two annealing RNA strands sharing 95 to 100% identity to a gene of interest (note that the antisense strand shares 95 to 100% identity to the sense strand), the language reciting 95% identity has been struck from the claims as amended. This amendment was unnecessary, but is nevertheless made simply to reduce the issues in the application. Although the Office is correct that the working examples show sequences that are 100% identical to segments of the example target genes, the specification correctly stated that the RNA produced from the claimed chimeric DNA may contain sense and antisense strands that are 95% identical to the target sequence and its antisense sequence. This is because the function of the sense strand and antisense strand are related to the ability to hybridize to a target sequence so that the former limitation was well within the range that a person of ordinary skill would recognize as capable of serving the intended function.

The specification provides adequate written description support for every individual aspect of the claimed invention and the claims taken as a whole. The invention is described in the claims by reciting sufficient structural elements in enough detail that the encompassed genus of chimeric DNA will provide the utilities asserted in the specification for the claimed invention and to distinguish the claimed invention from the prior art. The specification provides extensive guidance concerning the general principles of the claimed technology and provides working examples sufficient to demonstrate that the elements of the invention recited in the claims are sufficient for the claimed chimeric DNA to perform its intended function over the full range encompassed by the claims, i.e. to permit suppression of the expression of any gene of interest.

Thus, a person of ordinary skill in the art would have recognized that the description of the recited structural features of the claimed DNA could be combined, without limitation, with the knowledge of any of the myriad known gene sequences to provide a useful chimeric DNA. This satisfies the principle of the written description requirement as recently stated by the Federal Circuit. *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005) ("The 'written description' requirement implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed.")

The Office has alleged that the description does not adequately describe chimeric DNA comprising sense and antisense sequences identical to any gene of interest. In view of the general applicability of the invention, the Office cannot reasonably expect that the Applicants would provide a working example, or even list, every known gene that might be a

gene of interest and describe the sequence every sense and antisense strand that may be constructed by reference to the known genes that would result in a chimeric gene as claims. It is well established that such a description is not required. The Federal Circuit has recently reiterated that

> When the prior art includes the nucleotide information, precedent does not set a per se rule that the information must be determined afresh." [*Capon*] at 1358. Rather, we explained that:
>
> > The descriptive text needed to meet these requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence. The law must be applied to each invention that enters the patent process, for each patented advance is novel in relation to the state of the science. Since the law is applied to each invention in view of the state of relevant knowledge, its application will vary with differences in the state of knowledge in the field and differences in the predictability of the science.
>
> [*Capon*] at 1357.
>
> Indeed, a requirement that patentees recite known DNA structures, if one existed, would serve no goal of the written description requirement.

Falkner v. Inglis, 79 USPQ2d 1001, 1008 (Fed. Cir. 2006)(citing *Capon*, *supra*).

The claimed chimeric DNA can be constructed as described in the specification using the known sequences of any of the myriad genes that may be of interest. Therefore, the scope of the description in the specification is commensurate with and adequate to support the genus of any gene of interest.

Finally, the Office has alleged that the specification does not describe the claimed chimeric DNA wherein the DNA comprises any intron sequence heterologous to the sense strand. Intron sequences and the structural features by which they may be recognized are and were known in the art. Applicants respectfully submit that the Office has not adduced any reason to doubt that the chimeric DNA as claimed can be constructed using any known intron sequence. As discussed above, Applicants are under no requirement to described what is known in the art, even when the invention is directed to biological macromolecules.

That the chimeric DNA of the invention can be made using any known intron sequence has been born out by subsequent publication. The Examiner's attention is drawn to a publication by Wesley et al. 2001 (submitted concurrently herewith with the enclosed information disclosure statement), which was discussed during the interview. Wesley et al. proves that an intron sequence other than the pyruvate orthophosphate dikinase 2 intron 2 exemplified in the specification can be used. The table on page 587 of the publication indicates efficient silencing using at least two other introns (Δ12a and Δ12c introns).

Also, as pointed out at that time, this publication supports the fact, as conveyed by the specification, that the location of the intron is not critical. Indeed, as pointed out on page 585 of this publication, sentence spanning the 1st and 2nd column, the presence of an intron in the 5' portion of the transcribed region, in the absence of any further intron between the sense and antisense strands, led to efficient silencing.

The Examiner's attention is also drawn to a selection of other publications using intron sequences other than the pdk2 intron 2, based on the teaching of the present application attached to the information disclosure statement submitted concurrently herewith. Note that most of these publications make explicit reference to Smith et al. 2000, Nature, 407, 319-320 (submitted with the Reply filed on September 12, 2005) which reports examples from the current application and was co-authored by named inventors of the application.

Samuel and Ellis 2002 - The Plant Cell, 14: 2059-2069 describe efficient gene silencing in plants using a hairpin construct as described by Smith et al. 2000 (see page 2064 1st column, three lines from bottom), and as described in the present specification, comprising the fourth intron of AtMPK6 gene (page 2066, 2nd column, section entitled "intron spliced Hairpin loop RNA-SIPK construct", lines 3-5).

Acosta-Garcia and Vielle-Calzada 2004 - The Plant Cell, 16: 2614-2628 describe efficient gene silencing in plants using a hairpin construct as described by Smith et al. 2000 (page 2617, 2nd column, line 17) , and as described in the present specification, comprising an intron of chalcone synthase gene (page 2617, 2nd column, lines 13-14, page 2625, 2nd column, lines 20-22 and Fig 4A - page 2619).

Guo et al., 2003 - The Plant Journal, 34: 383-392 describe efficient gene silencing in plants using a hairpin construct as described by Smith et al. 2000 (page 383, sentence spanning 1st and 2nd column), and as described in the present specification, comprising the third intron of the actin 11 gene (Figure 1, page 384; legend to Figure 1, page 384, line 8 and page 391, 1st column, section entitled "Plasmid construction", lines 2-4).

Chen et al., 2003 - The Plant Journal, 36: 731-740 describe efficient gene silencing in plants using a hairpin construct as described by Smith et al. 2000 (page 732, 1st column, line 33), and as described in the present specification, comprising intron 1 of potato GA20 oxidase gene (Figure 1, page 733 legend to figure 1; page 733, lines 6-7 and page 738 1st column section entitled "Plasmid construction and plant transformation", lines 8-9).

Byzova et al., 2004 - Planta, 218:379-387 describe efficient gene silencing in plants using a hairpin construct as described by Smith et al. 2000 (page 384, 2nd column, line 9) , and as described in the present specification, comprising Intron IV2 from the potato ST-LS1 gene (page 380, 2nd column, section entitled "Plasmid construction", lines 18-19).

Lee et al., 2003 - Methods, 30: 322-329 describe efficient gene silencing in animals using a hairpin construct as described by Smith et al. 2000 (page 324, 2nd column, lines 1-3), and as described in the present specification, comprising intron 2 of the white gene (Legend to figure 4, page 327, line 1; page 324, 2nd column, lines 31-34)

Further examples of efficient gene silencing using hairpin constructs with introns are provided by Li et al., 2005 – The Plant Cell, 17:859-875 (first intron of the GhTUB1 gene-page 873 1st column, 4th section) and O'Brien et al. 2002 – The Plant Journal 32:985-996 (intron from HD2 histone deacetylase gene-page 994, 2nd column lines 9-10).

It will be abundantly clear from this selection of publications reporting work using hpRNA constructs comprising introns as taught by the present application and reported by Smith et al. 2000 that indeed any intron can be used in accordance with the written description and claims.

Accordingly, combining the teaching of the specification with knowledge available in the art on intron sequences, a person of ordinary skill would have appreciated the invention encompassed any species of the claimed genus of chimeric constructs having the recited structural features and further comprising any intron in any position as illustrated by the above list of publications inspired by the teaching of the current specification. It is not practical nor required for applicants to recite known structures *See e.g., Capon* and *Falkner*, *supra*. The applicants have provided general teachings of how to select and recombine known DNA structures to make a novel and non-obvious invention. The applicants provided working examples of the production of the claimed chimeric genes.

For at least the foregoing reasons, the written description of the specification is indeed adequate to satisfy the principles of the written description requirement of 35 U.S.C. § 112, first paragraph as explained by the Federal Circuit. Therefore, withdrawal of the rejection is appropriate and earnestly requested.

CONCLUSION

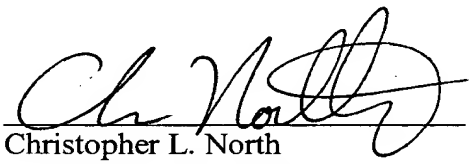
In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned concerning such questions so that prosecution of this application may be expedited.

The Director is hereby authorized to charge any appropriate fees that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: November 22, 2006 By: 

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